MAY 23 2008

510(k) Summary of Safety and Effectiveness
LOCI Thyroid Calibrator

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K081103

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714

Contact Information:
Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714
Attn: Yuk-Ting Lewis
Tel: 302-631-7626

Date of Preparation:
April 14, 2008

2. Device Name / Classification

LOCI Thyroid Calibrator / 21 CFR 862.1150 / Class II

3. Identification of the Predicate Device

LOCI Thyroid Calibrator, K073604

4. Device Description

The LOCI Thyroid Calibrator is a liquid, bovine serum albumin based product containing thyroid stimulating hormone and thyroxine. The calibrator levels and their assigned values are:

	Level 2	Level 3	Level 4	Level 5	Level 6
FT4L	----	0.8 ng/dL	2.0 ng/dL	4.0 ng/dL	8.4 ng/dL
TSHL	0.00 µIU/mL	4.00 µIU/mL	20.00 µIU/mL	50.00 µIU/mL	105.00 µIU/mL

5. Device Intended Use

The LOCI Thyroid Calibrator is an in vitro diagnostic product for the calibration of the FT4L and TSHL methods on the Dimension® EXL™ with LM system.

6. Medical device to which equivalence is claimed and comparison information

The LOCI Thyroid Calibrator is substantially equivalent to the calibrator previously cleared under K073604. The LOCI Thyroid Calibrator contains human thyroid stimulating hormone and thyroxine for calibrating the Dimension® TSHL and FT4L methods.

Feature	**Predicate Device:** **LOCI Thyroid Calibrator**	**New Device:** **LOCI Thyroid Calibrator**
Intended Use	The LOCI Thyroid Calibrator is used to calibrate the Dimension® FT4L method on the Dimension® EXL™ with LM system.	The LOCI Thyroid Calibrator is used to calibrate the Dimension® FT4L and TSHL methods on the Dimension® EXL™ with LM system.
Analyte and Matrix	The LOCI Thyroid Calibrator contains thyroxine in a bovine serum albumin matrix.	The LOCI Thyroid Calibrator contains human thyroid stimulating hormone and thyroxine in a bovine serum albumin matrix.
Form	The calibrators are in liquid form.	
Calibrator levels	The LOCI Thyroid Calibrator kit contains Levels 3 through 6.	The LOCI Thyroid Calibrator kit contains Levels 2 through 6. Levels 3 through 6 are used to calibrate the FT4L method. Levels 2 through 6 are used to calibrate the TSHL method.
Stability	The stability of the calibrators is established through real-time data on 3 lots of product. Testing is conducted at multiple time points and must pass pre-defined acceptance criteria.	
Traceability	The calibrator is traceable to an internal master pool for FT4.	The calibrator is traceable to an internal master pool for FT4 and to the WHO standard for TSH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 23 2008

Siemens Healthcare Diagnostics, Inc.
c/o Yuk-Ting Lewis
P.O. Box 6101, M/S 514
Newark, DE 19714

Re: k081103
Trade/Device Name: LOCI Thyroid Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: May 13, 2008
Received: May 14, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081103

Device Name: LOCI Thyroid Calibrator

Indications For Use:

The LOCI Thyroid Calibrator is an in vitro diagnostic product for the calibration of the FT4L and TSHL methods on the Dimension® EXL™ with LM system.

Prescription Use ___x___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081103